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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ORELLENE SEABOLD, Plaintiff, vs. BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER HEALTHCARE LLC; GENERAL ELECTRIC COMPANY; GE HEALTHCARE, INC.; COVIDIEN, INC.; MALLINCKRODT, INC.; and BRACCO DIAGNOSTICS, INC. Defendants.	Case No: ORIGINAL COMPLAINT DEMAND FOR JURY TRIAL

EMC

Plaintiff, Orellene Seabold, (hereinafter "Plaintiff") alleges as follows:

NATURE OF THE CASE

1. Plaintiff Orellene Seabold ("Ms. Seabold" or "Plaintiff") has nephrogenic systemic fibrosis ("NSF"). NSF is an incurable, painful, and deadly disease. Ms. Seabold contracted NSF as a result of receiving intravenous injections of gadolinium-based contrast agents manufactured by the Defendants. Gadolinium-based contrast agents are not safe for use in individuals such as Plaintiff who have impaired kidney function. Defendants represented that the gadolinium-based contrast agents were safe and failed to warn of the risks associated with gadolinium-based contrast agents.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 28 USC § 1332. Plaintiff is a citizen of a state that is different from the states where Defendants are incorporated and have their respective principal places of business. The amount in controversy for this case exceeds $75,000. Venue pursuant to

28 USC § 1391(c) is proper because Defendants have sufficient contacts within the City and County of San Francisco, California to subject each of them to personal jurisdiction.

INTRADISTRICT ASSIGNMENT

3. On information and belief, a substantial part of the events or omissions which give rise to the claim occurred in the City and County of San Francisco.

PARTIES

Plaintiff

4. Orellene Seabold is a resident of the State of Tennessee.

Defendants

5. Defendants Bayer HealthCare Pharmaceuticals, Inc. and Bayer Healthcare LLC (jointly referred to as "Bayer") manufacture, market, and sell Magnevist, a gadolinium-based contrast agent that, on information and belief, was injected into Plaintiff.

6. Defendant Bayer HealthCare LLC is a Delaware business entity with its principal place of business in New York.

7. Defendant Bayer HealthCare Pharmaceuticals, Inc. is a Delaware business entity with its principal place of business in New Jersey. Defendant Bayer HealthCare Pharmaceuticals, Inc. is the U.S.-based pharmaceuticals unit of Bayer Healthcare LLC.

8. At all times relevant to this complaint, Bayer was in the business of designing, licensing, manufacturing, distributing, selling, marketing, promoting, and introducing Magnevist into interstate commerce.

9. Defendants General Electric Company and GE Healthcare, Inc. (jointly referred to as "GE") manufacture, market, and sell Omniscan, a gadolinium-based contrast agent that, on information and belief, was injected into Plaintiff.

10. Defendant General Electric Company is a New York business entity with its principal place of business in Connecticut.

11. Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of business in New Jersey.

12. At all times relevant to this complaint, GE was in the business of designing, licensing,

manufacturing, distributing, selling, marketing, promoting, and introducing Omniscan into interstate commerce.

13. Defendants Covidien Inc. and Mallinckrodt, Inc. (collectively referred to as "Covidien") manufacture, market, and sell OptiMARK, a gadolinium-based contrast agent that, on information and belief, was injected into Plaintiff.

14. Defendant Covidien, Inc. is a Delaware corporation with its principal place of business in New Hampshire.

15. Defendant Mallinckrodt, Inc. is a Delaware corporation with its principal place of business in Missouri. Mallinckrodt is a business unit of Covidien, Inc.

16. At all times relevant to this complaint, Covidien was in the business of designing, licensing, manufacturing, distributing, selling, marketing, promoting, and introducing OptiMARK into interstate commerce.

17. Defendant Bracco Diagnostics, Inc. ("Bracco") manufactures, markets, and sells MultiHance and ProHance, gadolinium-based contrast agents that, on information and belief, were injected into Plaintiff.

18. Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business in New Jersey.

19. At all times relevant to this complaint, Bracco was in the business of designing, licensing, manufacturing, distributing, selling, marketing, promoting, and introducing MultiHance and ProHance into interstate commerce.

20. The Bayer, GE, Covidien, and Bracco Defendants are collectively referred to as Defendants.

FACTS

21. Ms. Seabold was diagnosed with NSF in or around September of 2007.

22. NSF is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin after receiving a gadolinium-based contrast agent injection. These fibrotic and edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in contractures. NSF often progresses to painful inhibition of the ability to use the arms, legs, hands,

feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a "woody" texture and are accompanied by burning, itching, or severe pain in the areas of involvement. NSF also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart, liver, and musculature, and that can inhibit their ability to function properly and may lead to death. NSF is a progressive disease for which there is no known cure.

23. NSF is a man-made disease. It only occurs in patients who have received a gadolinium-based contrast agent.

24. Gadolinium is a highly toxic heavy metal. It does not occur naturally in the human body. The only known route for gadolinium to enter the human body is injection of a gadolinium-based contrast agent.

25. Because gadolinium is toxic, it has to be coated to keep it from coming in contact with human tissue when injected. This coating process is called chelation.

26. Gadolinium is eliminated from the body by the kidneys. Gadolinium-based contrast agents are not safe if the chelate separates from the gadolinium, which is what happens over time if kidneys are not functioning properly. Individuals with impaired kidney function risk dechelation, and cannot efficiently or quickly eliminate gadolinium from their bodies. Defendants never tested the safety of their gadolinium-based contrast agents in individuals with kidney impairment.

27. On information and belief, the gadolinium-based contrast agents injected into Plaintiff were manufactured by Defendants.

28. In pre-clinical studies during which gadolinium-based contrast agents were injected into laboratory animals, consistent patterns of toxicity including nephrogenic fibrotic changes in the kidneys and other body organs occurred.

29. During the years that Defendants have manufactured, marketed, distributed, sold, and administered gadolinium-based contrast agents, there have been numerous case reports, studies, assessments, papers, and other clinical data that have described and/or demonstrated NSF in connection with the use of gadolinium-based contrast agents.

30. Plaintiff received MRIs and/or MRAs utilizing gadolinium-based contrast agents.

31. Plaintiff had impaired kidney function at the time she received her first injection of

gadolinium-based contrast agent and continued to have impaired kidney function at the time she received each subsequent injection of gadolinium-based contrast agent.

32. During the time period when Plaintiff received injections of Defendants' gadolinium-based contrast agents, Defendants knew or should have known that the use of gadolinium-based contrast agents created a risk of serious bodily injury and death in patients with impaired kidney function.

33. Defendants failed to warn Plaintiff and her healthcare providers about the serious health risks associated with gadolinium-based contrast agents, and failed to disclose the fact that there were safer alternatives.

34. As a direct and proximate result of receiving injections of gadolinium-based contrast agents manufactured, marketed, distributed, and sold by Defendants, Plaintiff developed NSF.

35. Defendants have repeatedly and consistently failed to advise consumers and/or their healthcare providers of the causal relationship between gadolinium-based contrast agents and NSF in patients with kidney impairment. Defendants knew or should have known of the risk of NSF posed by gadolinium-based contrast agents to individuals with impaired kidney function years before they finally issued warnings.

36. It was not until September 2007 that Bayer, GE, Bracco, and Mallinckrodt finally sent letters to healthcare providers warning them of the risk of NSF to kidney impaired individuals who received MRIs using gadolinium-based contrast agents.

37. Had Plaintiff and/or her healthcare providers been warned about the risks associated with gadolinium-based contrast agents, she would not have been administered gadolinium-based contrast agents and would not have been afflicted with NSF.

38. As a direct and proximate result of Plaintiff being administered gadolinium-based contrast agents, she has suffered severe physical injury and pain and suffering, including, but not limited to, the effects of NSF. Plaintiff's physical injuries and pain and suffering will inevitably worsen over time and will in all likelihood lead to death.

39. As a direct and proximate result of being administered gadolinium-based contrast agents, Plaintiff suffered and continues to suffer significant mental anguish and emotional distress and

will continue to suffer significant mental anguish and emotional distress in the future.

40. As a direct and proximate result of being administered gadolinium-based contrast agents, Plaintiff has also incurred medical expenses and other economic damages and will continue to incur such expenses in the future.

DISCOVERY RULE & FRAUDULENT CONCEALMENT

41. The discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew or through the exercise of reasonable care and diligence should have known of the existence of her claims against all Defendants. The nature of Plaintiff's injuries and damages, and their relationship to gadolinium-based contrast agents used in conjunction with MRIs and MRAs, was not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiff, until a time less than two years before the filing of this Complaint. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

42. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiff the nature of Plaintiff's injury and the connection between the injury and all Defendants' tortious conduct.

FIRST CAUSE OF ACTION

STRICT LIABILITY: FAILURE TO WARN

43. Plaintiff incorporates by reference and realleges each paragraph set forth above.

44. Defendants' gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents, were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing. Defendants knew or should have known that their products created significant risks of serious bodily harm and death to consumers. Defendants failed to adequately warn consumers and their healthcare providers of such risks.

45. Because of Defendants' failure to provide adequate warnings with their products, Plaintiff was injected with gadolinium-based contrast agents that the Defendants manufactured, designed, sold, supplied, marketed, or otherwise introduced into the stream of commerce. Those

gadolinium-based contrast agents are the legal cause of Plaintiff's physical injuries, harm, damages, and economic loss. Plaintiff will continue to suffer such harm, damages, and economic loss in the future.

SECOND CAUSE OF ACTION

STRICT LIABILITY: DESIGN DEFECT

46. Plaintiff incorporates by reference and realleges each paragraph set forth above.

47. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.

48. The gadolinium-based contrast agents manufactured and supplied by Defendants were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of the products exceeded the benefits associated with their design or formulation, or were more dangerous than an ordinary consumer would expect.

49. The foreseeable risks associated with the design or formulation of gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents, include, but are not limited to, the fact that the design or formulation of gadolinium-based contrast agents are more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

50. As a direct and proximate result of Plaintiff being administered gadolinium-based contrast agents as manufactured, designed, sold, supplied, marketed, and introduced into the stream of commerce by Defendants, Plaintiff has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

THIRD CAUSE OF ACTION

STRICT LIABILITY: FAILURE TO ADEQUATELY TEST

51. Plaintiff incorporates by reference and realleges each paragraph set forth above.

52. Defendants advised consumers and the medical community that gadolinium-based contrast agents were safe for use. Defendants failed to adequately test gadolinium-based contrast agents with respect to their use by consumers with kidney impairment.

53. Had Defendants adequately tested the safety of gadolinium-based contrast agents for use by consumers with kidney impairment and disclosed those results to the medical community or the public, Plaintiff would not have been administered gadolinium-based contrast agents.

54. As a direct and proximate result of Defendants' failure to adequately test the safety of gadolinium-based contrast agents and as a direct and proximate result of Plaintiff being administered gadolinium-based contrast agents as manufactured, designed, sold, supplied, marketed, and introduced into the stream of commerce by Defendants, Plaintiff has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

FOURTH CAUSE OF ACTION

NEGLIGENCE

55. Plaintiff incorporates by reference and realleges each paragraph set forth above.

56. Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, labeling, marketing, sale and/or distribution of gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm and adverse events.

57. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, marketing, or distribution of gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents in that they knew or should have known that the products could cause significant bodily harm or death and were not safe for use by certain types of consumers.

58. Defendants failed to exercise ordinary care in the labeling of gadolinium-based contrast agents and the labeling of MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents and failed to issue to consumers and their health care providers adequate warnings concerning the risks of serious bodily injury or death due to the use of gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.

59. Despite the fact that Defendants knew or should have known that gadolinium-based

contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents posed a serious risk of bodily harm to consumers, Defendants unreasonably continued to manufacture and market gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents for administration to MRI and MRA patients with kidney impairment and failed to exercise reasonable care with respect to post-sale warnings and instructions for safe use.

60. At all relevant times, it was foreseeable to Defendants that consumers like Plaintiff would suffer injury as a result of their failure to exercise ordinary care as described above.

61. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered physical injuries, harm, damages, and economic loss and will continue to suffer such harm, damages and economic loss in the future.

62. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such, Plaintiff is entitled to exemplary damages.

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

63. Plaintiff incorporates by reference and realleges each paragraph set forth above.

64. Defendants supplied the public and Plaintiff's healthcare providers with materially false and incomplete information with respect to the safety of their gadolinium-based contrast agents.

65. The false information supplied by Defendants was that gadolinium-based contrast agents were safe.

66. In supplying this false information, Defendants failed to exercise reasonable care.

67. The false information communicated by Defendants to Plaintiff and her healthcare providers was material and Plaintiff justifiably relied in good faith on the information to her detriment.

68. As a direct and proximate result of Defendants' misrepresentations, Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

SIXTH CAUSE OF ACTION

FRAUD

69. Plaintiff incorporates by reference and realleges each paragraph set forth above.

70. Defendants knowingly and intentionally made materially false and misleading representations to Plaintiff's healthcare providers and to the public, to the effect that gadolinium-based contrast agents were safe for use and that their labeling, marketing, and promotional materials fully described all known risks associated with their product.

71. Defendants' representations were in fact false. Gadolinium-based contrast agents are not safe for use and Defendants' labeling, marketing, and promotional materials did not fully describe all known risks of the products.

72. Defendants had actual knowledge that gadolinium-based contrast agents created an unreasonable risk of serious bodily injury and death to consumers, especially patients with kidney impairment.

73. Defendants knowingly and intentionally omitted this information from their labeling, marketing, and promotional materials and instead, labeled, promoted, and marketed their products as safe for use in order to increase and sustain sales.

74. When Defendants made representations that gadolinium-based contrast agents were safe for use, they knowingly and intentionally concealed and withheld from Plaintiff, her healthcare providers, and the public, the fact that their gadolinium-based contrast agents are not safe for use in consumers with kidney impairment.

75. Defendants had a duty to disclose that gadolinium-based contrast agents are not safe for use in patients with kidney impairment. Defendants had superior knowledge of these facts that were material to Plaintiff and her healthcare providers' decisions to use gadolinium-based contrast agents.

76. Plaintiff and her healthcare providers reasonably and justifiably relied on the Defendants' representations that gadolinium-based contrast agents were safe for human use and that Defendants' labeling, marketing, and promotional materials fully described all known risks associated with the products.

77. Plaintiff did not know and could not have learned of the facts that the Defendants

omitted and suppressed. The facts suppressed and concealed by the Defendants are material. Had Plaintiff and her healthcare providers known that gadolinium-based contrast agents are not safe for use in patients with renal insufficiency, Plaintiff would not have been injected with gadolinium-based contrast agents.

78. As a direct and proximate result of Defendants' misrepresentations and concealment, Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

79. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such Plaintiff is entitled to exemplary damages.

SEVENTH CAUSE OF ACTION

FRAUD: CONCEALMENT, SUPPRESSION OR OMISSION OF MATERIAL FACTS

80. Plaintiff incorporates by reference and realleges each paragraph set forth above.

81. Defendants omitted, suppressed, or concealed material facts concerning the dangers and risk associated with the use of their gadolinium-based contrast agents, including but not limited to the risks to patients with kidney impairment of developing NSF, and the fact that safer alternatives were available. Further, Defendants purposely downplayed and understated the serious nature of the risks associated with use of their gadolinium-based contrast agents in order to increase and sustain sales.

82. As a direct and proximate result of Defendants' concealment of material facts, Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

83. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such Plaintiff is entitled to exemplary damages.

EIGHTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

84. Plaintiff incorporates by reference and realleges each paragraph set forth above.

85. Defendants expressly warranted that gadolinium-based contrast agents were safe and effective.

86. The gadolinium-based contrast agents manufactured and sold by Defendants did not conform to these express representations because they cause serious injury to consumers when administered in recommended dosages.

87. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

88. Plaintiff incorporates by reference and realleges each paragraph set forth above.

89. At the time Defendants designed, manufactured, marketed, sold, and distributed gadolinium-based contrast agents, Defendants knew of the use for which gadolinium-based contrast agents was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

90. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether gadolinium-based contrast agents were of merchantable quality and safe for their intended use and upon Defendants' implied warranty as to such matters.

91. Contrary to such implied warranty, gadolinium-based contrast agents were not of merchantable quality or safe for their intended use because the product was unreasonably dangerous as described above.

92. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

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TENTH CAUSE OF ACTION

VIOLATION OF TENNESSEE CONSUMER PROTECTION STATUTES

93. Plaintiff incorporates by reference and realleges each paragraph set forth above.

94. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code Ann. § 47-18-109(a)(1) *et seq.* including but not limited to the following:

a. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance, or ProHance for use with MRAs and other off-label uses by impliedly representing that such products are approved for use with MRAs and other off-label uses, when in fact there is no such approval;

b. Representing that gadolinium-based contrast agents are safe and effective for all patients, including patients with kidney impairment, when in fact they are not;

c. Representing that MRIs and MRAs using gadolinium-based contrast agents are safer or more effective than other imaging methods that do not require the use of gadolinium-based contrast agents when in fact they are not;

d. Marketing, promoting, or selling their products as safer or superior to other brands of gadolinium-based contrast agents;

e. Marketing, promoting, or selling Magnevist, Omniscan, OptiMark, MultiHance, or ProHance as inert or with words to that effect;

f. Marketing, promoting, or selling Magnevist, Omniscan, OptiMark, MultiHance, or ProHance for use with MRAs or other off-label uses by expressly or impliedly representing that they are safe for such use; and

g. Remaining silent despite their knowledge of the growing body of evidence regarding the danger of NSF and doing so because the prospect of huge profits outweighed health and safety issues.

95. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive actions or practices, Plaintiff was administered gadolinium-based contrast agents and has suffered serious physician injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, loss of consortium, and other non-economic damages in an amount to be determined at trial of this action;
2. Past and future medical expenses, income, and other economic damages in an amount to be determined at trial of this action;
3. Punitive damages in an amount to be determined at trial of this action;
4. Pre- and post-judgment interest;
5. Attorneys' fees, expenses, and costs; and
6. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury.

Respectfully submitted this 7th day of March, 2008.

LEVIN SIMES KAISER & GORNICK LLP

By: _____

Debra DeCarli, Esq.